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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/714,586

11/14/2003

Timothy J. Patrick

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1671

38732 7590 09/05/2008

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EXAMINER

LACYK, JOHN P

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

09/05/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/714,586 | Applicant(s) PATRICK ET AL. | |
| | Examiner John P. Lacyk | Art Unit 3735 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7-28 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-28 and 31-33 is/are rejected.
- 7) ☒ Claim(s) 30 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>7/30/08</u> . | 6) <input type="checkbox"/> Other: _____ |

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/30/08 has been entered.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-3, 7-26 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams (5,429,582) in view of Shaw et al (6,918,869). Williams discloses a brachytherapy device for treating tissue surrounding a resected cavity having a catheter body member having proximal and distal portions and an expandable member that defines a spatial volume. The volume is configured to receive a radiation source that would inherently provide a three-dimensional isodose profile that is substantially similar in shape to the expandable surface member. The embodiment as shown in Figure 7 further includes a treatment agent that is delivered to adjacent tissue when the device is positioned within the tissue cavity. Williams uses a catheter and porous balloon to deliver a treatment agent to the body. Williams discloses the claimed device and method except for the treatment agent being releasably mated with the expandable surface member. Shaw et al discloses a device for delivering both

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radiation therapy and biologically active materials or “treatment agents” and teaches (column 6, lines 6-42) that a biologically active material can be incorporated into the ends of the stent by various devices known to those skilled in the art such as coating the active material such that the agent is releasably mated to the device. Shaw et al also teaches that the active material could be delivered through a separate catheter and balloon. Therefore a modification of Williams such that the treatment agent is delivered by releasably mating the agent to the device instead of using a catheter and balloon would have been obvious in view of the teachings of Shaw et al which teaches that both ways are well known to releasably deliver a treatment agent to the desired area within the body and such a modification would be the mere substitution of one well known way to deliver a treatment agent for another.

Claims 27 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Williams and Shaw et al as applied to claims above, and further in view of Tam et al (6,458,069).

While embodiments of Williams are directed to cavities created by removing brain tumors, Williams also states that tumors in other sites is also included (column 1, line 64- column 2, line 2); also Tam et al teaches that the device while shown being used in a body lumen is well known to use any other location accessible by catheter which may benefit from radiation delivery including surgically created pathways, esophagus, urethra, ureters, etc. Therefore in view of the teachings to use the device as claimed in

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claims 27, 31-33 would have been obvious to one skilled in the art since these are well known places within the body to use radiation sources for therapy.

Claim 30 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Kaplan and Mavity et al are cited to further show that it is well known in the art to use a treatment agent that is releasably mated to different devices used within the body.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John P. Lacyk whose telephone number is (571)272-4728. The examiner can normally be reached on 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Chuck Marmor, II can be reached on 571-272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

J.P. Lacyk

/John P Lacyk/
Primary Examiner, Art Unit 3735